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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,813	03/06/2002	Kelly Huang	JBP-581	8501

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EXAMINER	
NOLAN, PATRICK J	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 03/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/091,813	HUANG ET AL.	
	Examiner	Art Unit	
	Patrick J. Nolan	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *7 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-16 and 18-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1-9-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 1-36 are pending.

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 24-33 have been renumbered claims 27-36.

3. It is noted the 1449 form submitted on 3-6-02 when the original application was filed is not part of the image file wrapper. Applicant is requested to resubmit the 1449 form, as the references AA-AX submitted on 3-6-02 have been considered.

4. It is noted the European search report submitted in the IDS submitted 1/9/04 has been considered but it has been lined through as it is not appropriate for publishing on the face of a an issued US Patent.

5. Applicant's election with traverse of the species found in claim 2 and 6 in the reply filed on 12-10-04 is acknowledged. The traversal is on the ground(s) that it would not be unduly burdensome to search all of the species. This is not found persuasive for reasons set forth in the species election.

The requirement is still deemed proper and is therefore made FINAL.

6. Claims 7 and 17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12-10-04.

7. The claims being examined in the current office action are claims 1-6, 8-16 and 18-36.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-6, 8-16 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly et al. (reference AL submitted in IDS received 3-6-02) in view of Perkins et al., 1997, (reference AG submitted in the IDS received 3-6-02).

Reilly et al., teaches the detection of skin irritation to external aggression by detecting prostaglandin E2 and IL-1-alpha in an EIA (PGE2) and in an ELISA (IL-1 alpha) using cellotape, which causes a small erythmatous patch. Reilly further teaches collecting secretions from the surface of the skin, measuring a baseline level of eicosanoid in the secretions, exposing said skin to an external aggression, then collecting secretion from the surface of skin and again measuring the level of eicosanoid in the secretions and comparing the levels of eicosanoid both before and after exposure of external aggression to skin (see methods section and table 1 in particular). Reilly further teaches measuring IL-1 alpha before and skin exposure. Reilly further teaches normalizing the eicosanoid levels by measuring protein levels in the skin secretions.

The claimed invention differs from the prior art teachings by the recitation of using an adhesive coated microporous plastic film to collect the skin secretions.

However, Perkins et al., specifically teaches the use of Sebutape™, an adhesive coated microporous plastic film, in the detection of IL-1-alpha by a non-invasive method to assess human skin irritation even in the absence of visible clinical irritation. Perkins et al., further

teaches that said tape can be easily applied in a clinical setter whether on infants, adults or geriatric adults.

Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to screen for skin irritation by detecting PGE2 and IL-1 alpha, as taught by Reilly et al., but substitute the use of Sebutape™, as taught by Perkins et al., because Sebutape™ is able to detect molecular mediators of skin irritation without being invasive and being able to detect said compounds prior to visible clinical irritation and because it can be easily applied in a clinical setting whether on infants, adults or geriatric adults.

11. Claims 11 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly et al., in view of Perkins et al., as applied to claim 11 above, and further in view of Mueller-Decker (reference AH on the IDS submitted 3-6-02).

Reilly et al., and Perkins et al., have discussed supra. However, Reilly et al., specifically teaches the measurement of PGE2 in a model of acute skin irritation, since it was already known that PGE2 plays a significant role in chronic skin irritation.

The claimed invention differs from the prior art teachings only by the recitation detecting eicosanoid levels 24 hours after exposure to the topical skin care product or external aggression.

However, Mueller-Decker et al., specifically teaches an increase level of PGE2 in skin irritated for 24 hours by causing invasive suction blisters.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to detect PGE2 in skin irritated for 24 hours as taught by Mueller-Decker using the non-invasive method taught by the combination of Reilly et al., and Perkins et al. because Sebutape™ is able to detect molecular mediators of skin irritation without being invasive and being able to detect said compounds prior to visible clinical irritation and because it can be easily applied in a clinical setting whether on infants, adults or geriatric adults.

12. Claims 23-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly et al. (reference AL submitted in IDS received 3-6-02) in view of Perkins et al., 1997, (reference AG submitted in the IDS received 3-6-02) and US Patent 4,281,061.

Reilly et al., and Perkins et al., have been discussed supra.

The claimed invention differs from the prior art teachings only by the recitation of a kit with said assays for eicosanoid and cytokine in said kit plus the adhesive coated microporous plastic film.

However, the '061 patent teaches reagents for performing immunoassays can be provided in kits as a matter of convenience, where the reagents are in predetermined ratios so as to optimize the sensitivity of the assay in the range of interest.

Therefore, one of ordinary skill in the art at the time of the invention would have been motivated to place the Sebutape™ taught by Perkins et al., and the commercial EIA for PGE2 and ELISA taught by Reilly et al., in a kit because kits allow reagents for performing immunoassays to be provided as a matter of convenience, where the reagents are in predetermined ratios so as to optimize the sensitivity of the assay in the range of interest. It is noted claim 30 is included because it is standard practice in performing commercial EIAs or ELISAs to use a multi-well plate for conducting the said immunoassays, as evidenced by applicant's specification in the use of a commercial EIA and ELISA, a multi-well immunoassay system was conducted.

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 1-10 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

In claims 1-10, skin irritation is to be measured, however there are no steps recited for the application of the irritant. Therefore the claim is incomplete.

15. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is 571-272-0847.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-272-0841.

Patrick J. Nolan, Ph.D.

Primary Examiner, Group 1640

February 25, 2005